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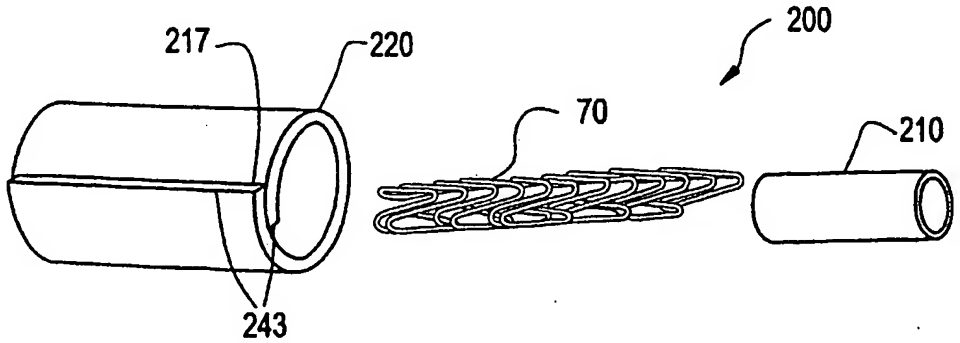
(54) Title: TUBULAR STENT-GRAFT COMPOSITE DEVICE AND METHOD OF MANUFACTURE



(57) Abstract: A stent-graft composite intraluminal prosthetic device comprises an elongated radially adjustable tubular stent, a PTFE stent cover positioned about the exterior surface of the stent and a PTFE liner positioned about the interior surface of the stent. One of the stent cover and the stent liner is formed of a seamless extruded tube and the other of the cover and the liner is formed of an elongated ePTFE sheet. The elongated sheet has opposed longitudinal edges which are joined to form a tubular structure. The stent has a plurality of open spaces extending between opposed interior and exterior surfaces to permit radial adustability, and the liner and cover are secured together through the open spaces of the stent. The liner and the cover may be adheringly secured through the spaces by an adhesive, or the cover and the liner may be laminated together through the open spaces of the stent.

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TUBULAR STENT-GRAFT COMPOSITE DEVICE AND METHOD OF MANUFACTURE

FIELD OF THE INVENTION:

The present invention relates generally to a tubular implantable prosthesis including a stent and graft composite structure used to repair and/or replace a body vessel. More particularly, the present invention relates to a multi-layered stent-graft composite device including a radially expandable stent and a graft formed of both a sheet of PTFE and an extruded PTFE tube.

BACKGROUND OF THE INVENTION:

It is well known to employ various endoprostheses for the treatment of diseases of various body vessels. Such endoprostheses are used to repair, replace or otherwise hold open a blocked or occluded body lumen such as that found in the vascular system.

One type of endoprosthesis is commonly referred to as a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful to open and support various lumens in the body. For example, stents may be used in the vascular system, urogenital tract and bile duct, as well as in a variety of other applications in the body. Endovascular stents have become widely used for the treatment of stenosis, strictures or aneurysms in various blood vessels. These devices are implanted within the vessel to open and/or reinforce collapsing or partially occluded sections of the vessel. Often, stents may be used in conjunction with a graft with provides additional support for blood flow through weakened sections of the blood vessel.

Various stent constructions are well known for such purposes. A common feature of such stent construction is that the stent includes an elongate tubular configuration having open spaces therethrough which permit the radial expansion of the stent. Stents generally are open ended and are radially expandable between a generally unexpanded insertion diameter

and an expanded implantation diameter which is greater than the unexpanded insertion diameter. Stents are often flexible in configuration, which allows them to be inserted through and conform to tortuous pathways in the blood vessels. The stent is generally inserted in a radially compressed state and expanded either through a self-expanding mechanism, or through the use of balloon catheters. For example, various stent constructions and their method of deployment are shown in U.S. Patent Nos. 4,503,569 to Dotter; 4,733,665 to Palmaz; 4,856,561 to Hillstead; 4,580,568 to Gianturco; 4,732,152 to Wallsten and 4,886,062 to Wiktor, all of which are incorporated herein by reference.

Another implantable prosthesis which is commonly used in the vascular system is a vascular graft. Grafts are typically used to repair or replace damaged portions of the blood vessel. Grafts are elongate tubular members exhibiting sufficient blood tightness to permit the graft to serve as a replacement for the damaged vessel. If the graft is thin enough and has adequate flexibility, it may be collapsed and inserted into a body vessel at a location within the body having diameter smaller than that of the intended repair site. An intraluminal delivery device, such as a catheter, is then used to move the graft into the repair site and expand the diameter of the graft therein to conform with the diameter of the vessel. In this manner, the graft provides a new blood contacting surface within the vessel lumen. The grafts are also microporous so as to permit tissue ingrowth and cell endotheliazation therealong. This improves the patency of the graft and promotes long term healing.

Vascular grafts may be formed of various materials such as synthetic textile materials. Grafts may also be formed of fluoropolymers such as expanded polytetrafluoroethylene (ePTFE). Grafts formed of ePTFE have the requisite degree of blood tightness yet exhibit a microstructure defined by interconnected nodes and fibrils which promotes tissue ingrowth and cell endotheliazation.

PTFE tubular structures for use as grafts may be formed in one or two manners. Tubes of PTFE may be formed in an extrusion process. The extruded tubes of PTFE may then be expanded and sintered to form expanded PTFE (ePTFE) exhibiting the requisite node

and fibril structure. Extruded tubes formed of ePTFE have well documented characteristics of blood tightness and porosity and also provide significant radial strength. Such radial strength enables the extruded PTFE tube to be used in combination with a radially expandable stent so as to form a stent/graft composite device. However, extrusion is impractical for the manufacture of thin walled tubes. As wall thickness decreases, processing by free extrusion becomes more difficult because the resulting tube is prone to kink, collapse or flatten during handling. Also, with free extrusion it is more difficult to control the inner diameter of the tube within tight tolerances which is required for medical applications.

Tubular PTFE structures may also be formed of sheets of ePTFE. Such sheets may be subsequently formed into a tubular configuration and applied to a stent to function in a stent/ graft environment. Use of PTFE sheets is beneficial in that sheets can be formed to have thinner wall thicknesses than conventional extruded tubes. Such thinner wall thicknesses enable the stent/graft composite device to be more easily intraluminally implanted by use of a delivery device.

This feature is especially important in the formation of a stent/graft composite device where a stent is provided with a PTFE cover about the exterior of the stent and a liner disposed about the interior surface of the stent. Thus, these composite devices have the beneficial aspects of a stent which is used to hold open a blocked or occluded vessel, and also a graft which is used to replace or repair a damaged vessel. While such composite device employing tubular structures formed of PTFE sheets are particularly beneficial due to the thinness at which they may be formed, these sheets may suffer from the lack of radial strength provided by extruded tubes. Thus, it may be difficult to maintain an internal liner and an external cover both formed from sheets where the stent must undergo contraction and expansion which is necessary to deliver and deploy the composite device at its ultimate location in the blood vessel.

Examples of the use of ePTFE endoprostheses are shown in U.S. Patent Nos. 5,700,285, 5,735,892 and 5,810,870, all of which are issued to Myers et al.. Each of the Myers patents discloses a stent-graft composite device wherein a tubular diametrically adjustable stent having has an exterior surface, a luminal surface, and either or both of an

exterior and luminal tubular covering of porous ePTFE. Each of the tubular coverings exhibits a longitudinal seam therealong which extends from an exterior surface to a luminal surface thereof. Individual thin films of ePTFE are used to form the tubular coverings such that the combined thickness thereof, exclusive of the stent, is less than about 0.10 mm. The Myers devices rely upon the inherent thinness of the films to provide a compact structure for intraluminal implantation.

An additional example is shown in commonly assigned U.S. Patent No. 5,800,512 to Lentz et al.. The Lentz patent discloses an implantable microporous ePTFE tubular vascular graft which includes a first ePTFE tube and a second ePTFE tube circumferentially disposed thereover. The first ePTFE tube exhibits a porosity sufficient to promote cell endotheliazation therealong. The second ePTFE tube exhibits enhanced radial tensile strength in excess of that of the first tube. Together, the tubes provide a graft device having an overall improved radial tensile strength and exhibiting increased porosity.

The procedures which utilize the above disclosed devices obviate the need for major surgical intervention and reduce the risks associated with such a procedure. It is desirable, however, to provide a stent-graft composite device which exhibits sufficient radial strength to permit the composite device to accommodate a radially expandable stent and yet be of sufficient thinness so as to permit intraluminal delivery by a conventional intraluminal delivery device.

The exhibition of sufficient radial strength enables the stent to withstand contraction and expansion within a biological lumen, while sufficient thinness enables insertion of the stent at a remote surgical site and subsequent movement into a small diameter body vessel.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an improved tubular-stent graft composite device.

It is another object of the present invention to provide a stent-graft composite device having increased radial strength to accommodate a radially expandable stent.

It is a further object of the present invention to provide a stent-graft composite device having sufficient radial thinness so as to permit intraluminal delivery by a delivery device, such as a catheter.

It is still a further object of the present invention to provide a stent/graft composite device having an outer tubular PTFE layer, an inner tubular PTFE layer and an elongate radially adjustable tubular stent disposed therebetween wherein one of said cover and said liner is formed of a seamless extruded tube and the other of said cover and said liner is formed of a PTFE sheet.

In the efficient attainment of these and other objectives, the present invention provides a composite stent-graft tubular prosthesis including an inner PTFE tubular structure and an outer PTFE tubular structure positioned about the inner PTFE tubular structure. A radially expandable stent is interposed between the inner and outer PTFE tubular structures. The interposed stent is formed from an elongated wire with a plurality of longitudinal spaces in an open tubular configuration. One of the outer tubular structure and the inner tubular structure comprises an extruded PTFE tube wherein the other of the outer tubular structure and the inner tubular structure comprises an elongated PTFE sheet having longitudinal edges which are joined together to form a tubular structure.

A method of making a stent-graft luminal prosthesis of the present invention is also disclosed. The method provides for the formation of a first PTFE tubular structure wherein the first tubular structure is one of an extruded PTFE tube or a PTFE sheet having a tubular configuration. A stent is positioned over said first PTFE tubular structure, the stent being a tubular configuration formed of an elongated wire. A second PTFE structure is then formed over said stent, with the second PTFE structure being the other of an extruded PTFE tube or PTFE sheet.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a preferred embodiment of a tubular stent-graft composite device of the present invention.

Figure 2 is a perspective view of an elongated extruded PTFE tube of the type used in the composite device of Figure 1.

Figure 3(a) is a cross-section of an elongated extruded PTFE tube of Figure 2 along section a-a.

Figure 3(b) is a transverse cross-section of an elongated extruded PTFE tube of Figure 2 taken along the line b-b.

Figure 4 is a perspective view of a sheet of PTFE of the type used in the composite device of Figure 1.

Figure 5 is a perspective view of a sheet of PTFE of Figure 4 formed into a tubular configuration.

Figure 6 is a side view of one embodiment of a stent which may be used in a stent-graft composite structure of the present invention.

Figure 7 is an exploded perspective view showing one embodiment of the stent-graft composite device of the present invention.

Figure 8 is a transverse cross-section of the composite device shown in Figure 7.

Figure 9 is an exploded perspective view showing a further preferred embodiment of the stent-graft composite device of the present invention.

Figure 10 is a transverse cross section of the composite device shown in Figure 9.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following is a description of the preferred embodiments of the present invention, in which like elements are identically numbered.

The prosthesis of the preferred embodiments of the present invention is a multi-layered composite tubular structure which is particularly suited for use as an endoprosthesis or vascular graft. In particular, an outer tubular cover is disposed about an inner tubular liner with a stent disposed therebetween. The stent is a tubular structure formed of an elongated wire having a plurality of open longitudinal spaces. Each of the tubular cover and liner is formed of polytetrafluoroethylene (PTFE), as PTFE exhibits superior biocompatibility. Further, PTFE is particularly suitable for vascular applications as it exhibits low thrombogenicity. Tubes formed of extruded PTFE may be expanded to form expanded polytetrafluoroethylene (ePTFE) tubes, where the ePTFE tubes have a fibrous state which is defined by elongated fibrils interconnected by spaced apart nodes. Also, ePTFE may be formed into elongated sheets having longitudinal edges which are joined together to form a tubular structure. In the present invention, one of the inner liner and outer cover is formed of such an ePTFE sheet and the other of said inner liner and outer cover comprises an ePTFE tube. The liner and cover may be adheringly secured to one another with a thermoplastic adhesive or laminated together through the open spaces of the stent.

An improved tubular stent-graft composite device 10 of the present invention is shown in Figure 1. Prosthesis 10 is a tubular structure having an elongated body 13. Prosthesis 10 comprises an outer tubular cover 12, an inner tubular liner 14 and a tubular stent 17 positioned therebetween. Stent 17 shown herein is just one example of the plurality of stent configurations which may be employed within the present invention.

A stent-graft composite device of the present invention is constructed by initially forming a first inner tubular liner 14, which is one of an extruded PTFE tube or a PTFE sheet. Stent 17 is then positioned over the inner tubular liner 14. An outer PTFE tubular cover 12

is then formed over stent 17, outer tubular cover being formed of the other of an extruded PTFE tube or sheet. PTFE tubular structures, whether extruded tubes or wrapped PTFE sheets, show advantageous biophysical compatibility qualities.

In a preferred embodiment of the present invention as described hereinbelow, tubular cover 12 comprises an extruded PTFE tube and tubular liner 14 comprises an ePTFE sheet having a pair of longitudinal edges which are joined together to form at seam 21 a tubular configuration. Once extruded, a tube of the type shown in cover 12 is expanded to form an ePTFE tube. The tube is expanded using differing process parameters (i.e., rates, deformation levels, temperature, etc.) to develop a desired microporous structure. The specifically designed structure of the resulting composite tube has defined properties of strength and porosity which yield a prosthesis 10 having long term patency and good healing characteristics, as well as superior radial strength characteristics.

Now the individual elements of an improved tubular stent-graft device of a preferred embodiment of the present invention may be described. Referring now to Figures 2, 3(a) and 3(b), an ePTFE tube 20 has an elongated body 31 and a longitudinal axis defined therethrough. Elongated body 31 is generally cylindrical and is defined by a tubular configuration wherein an inner diameter D_i and an outer diameter D_o define the thickness of the body. As shown in Figure 3(a), tube 20 has a uniform thickness extending along the length of body 31. As depicted in Figure 3(b), a transverse cross section of tube 20 at any point along the length thereof will show a nonvarying outer diameter D_o and a non-varying inner diameter D_i.

Tube 20 may be formed in a conventional extrusion process wherein a preform of PTFE and a lubricant are extruded through a tubular extruder barrel creating a tubular structure. The lubricant is removed from the extrudate, which is then expanded by stretching in a direction parallel to the longitudinal axis of the tubular structure at a temperature less than the melt point of PTFE. Typically, the tubular structure is longitudinally expanded by an expansion ratio of more than 2:1 (i.e. at least two times its original length). After completion of longitudinal expansion, the tubular structure is then sintered to effect amorphous-locking of the PTFE polymer.

Referring now to Figures 4 and 5, an ePTFE sheet or film 40 is shown. Sheet 40 includes a pair of longitudinal edges 43 and opposing edges 45 which define the parameters of a substantially planar body 49 therebetween. Body 49 has an upper surface 42 and an opposed lower surface 44, each of which is generally smooth. Body 49 is further defined by a thickness t which is sufficient for delivery of a prosthesis 10 (shown in Figure 1) into a vessel via an intraluminal delivery device.

Sheet 40 is then rolled into a tubular structure 50, shown in Figure 5. The tubular structure 50 may be formed by wrapping sheet 40 around a mandrel and forming a seam by overlapping the longitudinal edges of the sheet. After the seam is formed, the mandrel is placed into an oven which is set at a temperature above the melt-point of the sheet. The mandrel remains in the oven until the edges sufficiently adhere to one another. After heating, the mandrel is removed from the oven and allowed to cool. The mandrel is then removed from within the resulting tubular graft. Longitudinal edges 43 of sheet 40 can alternatively be joined together at seam 55 by a thermoplastic adhesive such as fluorinated ethylene propylene (FEP), creating a short overlap 57.

Tubular structure 50 has an outer surface 54 which corresponds to lower surface 44 of sheet 40 and a luminal surface 52 which corresponds to upper surface 42. Tubular structure 50 has a generally elongated body 51 with opposed open ends. Outer diameter D_o and inner diameter D_i of tube 50 defined by the thickness of sheet 40 wherein $D_o - D_i = t$.

In the case where the tubular structure 50 makes up the inner layer of prosthesis 10, longitudinal edges 43 need not be joined together so as to overlap. In such an embodiment (not shown), an adhesive is placed on the contacting surfaces of longitudinal edges 43 and melted just enough to bond edges 43 to one another.

The method of manufacturing the present stent-graft device comprises many steps performed by various types of machinery. First, a green tube of PTFE is formed through a conventional extrusion process as described above. PTFE exits the extruder tube in a tubular

structure having an approximate thickness of 170 μ (± 15 μ) before stretching. It is presumed that the thickness throughout the tubular structure is fairly uniform, yet not uniform enough to provide consistent radial strength through the structure without crimping thereof.

After the green tube is extruded, it is then expanded to form ePTFE. The tube is extended over a mandrel of approximately equal diameter to the extruded tube and clamped at both extremities. The tube is heat soaked at 500°F to soften the material and stretched at 500°F at the rate of 35 cm/sec. The tube is then partially sintered at 660°F for 14 minutes to 900% length or 1500% length. The tube is cooled at 65°F for about 5 minutes, then cooled at room temperatures for about 10 minutes. The tube is removed from the mandrel, inspected and inventoried for further manufacturing and use.

Measurement of the thickness of the tube can be accomplished by a plurality of methods. Two of the predominant methods of measuring thickness are the Thwing method and the snap-gauge technique, both of which are well-known in the art. After expansion, the thickness of the outer tube (1500% length) using the Thwing method is approximately .040mm while that of the inner tube (900% length) is approximately .070 mm. Using the snap-gauge technique, the thickness of the outer tube is .128 mm and that of the inner tube is .138 mm. Knowing the different results produced by the two methods is important in determining the applicability of the manufactured stent-graft prosthesis.

The stent is affixed to the exterior surface of a balloon on a balloon catheter so as to frictionally fit thereover. The balloon is inflated somewhat so as to expand the stent slightly. The previously fabricated outer tube is then placed into a catheter with one extremity of the tube extended past and folded over the periphery of the catheter. The balloon with the stent is then inserted into the catheter having the tube therein, after which the balloon is deflated so that the stent retains its expanded configuration. While the two components are in the catheter, an inner tube is radially compacted and inserted into the stent having the outer tube thereon. The inner tube is unfolded inside of the catheter (i.e, via a set of tweezers or similar device) and a mandrel is placed inside the tube-stent-tube combination, forcing the inner tube into a cylindrical configuration.

A heat shrink tube such as a silicone tube is subsequently placed over the entire structure, and ePTFE tape is used to tightly wrap the extremities of the heat shrink tube. The tube is then heat shrunk in a heated oven at elevated pressures, promoting conformance of the tube with the outer surface of the structure and initiating the sintering process wherein lamination occurs. The heat shrink tube is removed from the oven and permitted to cool. The ends of the PTFE tube(s) laminate are thereafter cut to match the contour of the stent, a process known as "scalloping" or "routing".

Although a wide variety of stents may be used, Figure 6 shows a perspective view of one particular stent which may be employed between outer tube 12 and inner tube 14 of prosthesis 10. The particular stent shown in Figure 6 is more fully described in commonly assigned U.S. Patent No. 5,575,816 to Rudnick, et al. Stent 70 is an intraluminally implantable stent formed of helically wound wire. Multiple windings 75 of a single metallic wire 72, preferably composed of a temperature-sensitive material such as Nitinol, provide stent 70 with a generally elongate tubular configuration which is radially expandable after implantation in a body vessel. The multiple windings 75 of stent 70 define open spaces 77 throughout the tubular configuration and define a central open passage 79 therethrough. The helically wound wire configuration not only ensures patency and flexibility, but the open spaces also allow adhering of the two tubular layers therethrough. Although this particular stent construction is shown and described with reference to the present invention, any stent of similar construction configured for the use anticipated herein may be utilized.

One embodiment of the present invention is shown in Figure 7. A graft-stent composite device 100 has an inner layer 110 comprising a tubular-configured ePTFE sheet such as shown and described with respect to Figure 4 above. Inner layer 110 has a thickness t sufficient for insertion into a stent 70. Stent 70 is correspondingly sized and shaped for insertion into tube 120 formed of an extruded and expanded PTFE such as that shown and described with respect to Figure 2 above. Referring to Figure 8, one benefit of having sheet 110 on the interior of the stent 70 is to eliminate the need to close sheet 110, thereby obviating any overlap or seams which may increase the thickness of the graft. Accordingly,

sheet 110 is depicted as having longitudinal edges 143 with a gap region 150 defined therebetween, indicating the lack of adherence between the edges. In the alternative, edges 143 could be secured to one another before insertion of the tubular structure into stent 70 via application of a thermoplastic adhesive to the contacting surfaces of edges 143.

Referring now to Figure 9, a preferred embodiment of the present invention is illustrated. A stent-graft composite device 200 includes an inner tubular structure 210, an outer tubular structure 220 and a stent 70 therebetween. In this embodiment, inner tubular structure 210 comprises an extruded PTFE tube of the type previously described and depicted in Figure 2. Tube 210 is adapted to be slidably disposed within the tubular configuration parameters of stent 70. As further illustrated in Figure 10, outer tubular structure 220 comprises an ePTFE sheet having overlapped longitudinal edges 243 which are secured together to form a seam 217. The thickness of the tubular structure 220, defined by inner diameter D_i and outer diameter D_o, is sufficient to enable delivery of the device 200 into a body vessel via an intraluminal delivery device, such as a catheter.

The composite device of the type shown in Figure 9 and 10 is formed by providing a stent 70 with both a luminal covering 210 is formed in a conventional production process as previously described and is slidably disposed within stent 70. Either or both of tube 210 and sheet 220 is provided with an adhesive thereon which permits adherence of the PTFE structures to one another through the stent openings and simultaneously allows adherence of stent 70 to either or both of the PTFE structures. The adhesive may be a thermoplastic adhesive and more preferably, a thermoplastic fluoropolymer adhesive such as FEP. Alternatively, the two coverings may be affixed by heating them above the melt point of PTFE adequately to cause them to thermally adhere.

The stent may be adhered to the inner PTFE tubular layer, the outer PTFE tubular layer, or both. Such adherence may be effected with or without the use of an adhesive. Additionally, when a stent with a plurality of open spaces or slots therethrough (such as wire stent 70) is utilized in the prosthesis 10 or devices 100 and 200, the inner and outer tubular layers may be adhered to each other through the spaces in the stent. Such adherence may be

accomplished with the use of an adhesive. Alternatively, the tubular layers may be adhered directly together through the spaces by the lamination of the layers. Sintering is one method of effecting such adherence.

Various changes and modifications can be made to the present invention. It is intended that all such changes and modifications come within the scope of the invention as set forth in the following claims.

WHAT IS CLAIMED IS:

1. A stent-graft composite intraluminal prosthetic device comprising:

an elongated radially adjustable tubular stent, defining opposed interior and exterior stent surfaces;

a PTFE stent cover positioned about the exterior surface of said stent; and

a PTFE stent liner positioned about the interior surface of said stent;

wherein one of said cover and said liner is formed of an extruded tube and the other of said cover and said liner is formed of a sheet.

2. A stent-graft composite device of claim 1 wherein said cover and said liner are formed of ePTFE having a porous structure defined by nodes and fibrils.

3. A stent-graft composite device of claim 1 wherein said stent liner is formed from said extruded tube.

4. A stent-graft composite device of claim 1 wherein said stent cover is formed from said extruded tube.

5. A stent-graft composite device of claim 1 wherein said stent liner is formed from a seamless sheet having opposed longitudinal edges.

6. A stent-graft composite device of claim 1 wherein said cover is an elongate sheet having opposed longitudinal edges and wherein said edges are joined to form a tubular structure.

7. A stent-graft composite device of claim 1 wherein said stent includes plural open spaces extending between said opposed interior and exterior surfaces so as to permit said radial adjustability, and wherein said liner and said cover are secured together through said open spaces of said stent.

8. A stent-graft composite device of claim 7 wherein said liner and said cover are adheringly secured.

9. A stent-graft composite device of claim 7 wherein said liner and said cover are laminated together through said open spaces of said stent.

10. An intraluminal tubular prosthesis comprising:

an elongate stent having a cylindrical stent wall with open spaces extending through said wall so as to permit radial expansion and contraction of said stent;

a PTFE sheet formed about said cylindrical stent wall on one of an interior and exterior wall surface thereof; and

an extruded PTFE tube positioned in engagement with the other of said interior and exterior wall surface.

11. A tubular prosthesis of claim 10 wherein said PTFE sheet is formed about said interior wall surface of said stent.

12. A tubular prosthesis of claim 11 wherein said PTFE sheet is seamless.

13. A tubular prosthesis of claim 10 wherein said PTFE sheet is formed about said exterior wall surface of said stent.

14. A tubular prosthesis of claim 10 wherein said PTFE sheet is an elongate member having opposed longitudinal edges and wherein said edges are joined to form a tubular structure.

15. A method of forming a stent-graft prosthesis comprising the steps of:

forming a first PTFE tubular structure;

positioning a stent over said first PTFE structure, said stent having a tubular configuration with a plurality of open spaces therethrough; and

forming a second PTFE tubular structure over said stent;

wherein one of said first and second PTFE tubular structures is a seamless extruded tube and the other of said first and second PTFE tubular structures is formed from a sheet.

16. A method of claim 15 further including the step of securing said first PTFE tubular structure to said second PTFE tubular structure through said open spaces of said stent.

17. A method of claim 16 wherein said first PTFE structure is adheringly secured to said second PTFE tubular structure.

18. A method of claim 16 wherein said first PTFE tubular structure and said second PTFE tubular structure are laminated together through said open spaces of said stent.

19. A method of forming a stent-graft prosthesis comprising the steps of:

providing a first PTFE tubular structure consisting of an interior surface and an exterior surface;

placing a tubular diametrically deformable stent circumferentially around the exterior surface of said first tubular structure;

and disposing a second PTFE tubular structure externally about said tubular diametrically deformable stent; wherein one of said first and second PTFE tubular structures is a seamless extruded PTFE tube and the other of said first and second PTFE tubular structures is formed from a sheet.

20. A method of claim 19 wherein said stent defines a tubular wall having a plurality of open spaces therethrough.

21. A method of claim 20 wherein said first PTFE tubular structure is adheringly secured to said second PTFE tubular structure through said open spaces of said stent.

22. A method of claim 21 wherein said first PTFE tubular structure as adhesively secured to said second PTFE tubular structure through said open spaces of said stent.

23. A method of claim 20 wherein said tubular wall of said stent has opposed inner and outer surfaces and wherein said first PTFE tubular structure is adheringly secured to said inner surface of said stent and said second PTFE tubular structure is adheringly secured to said outer surface if said stent.

FIG. 1

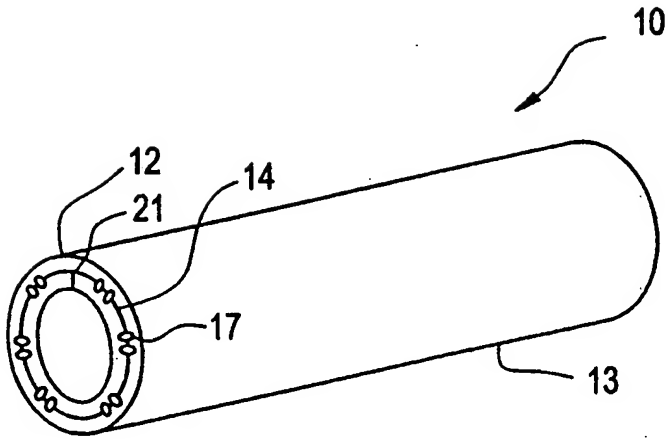


FIG. 2

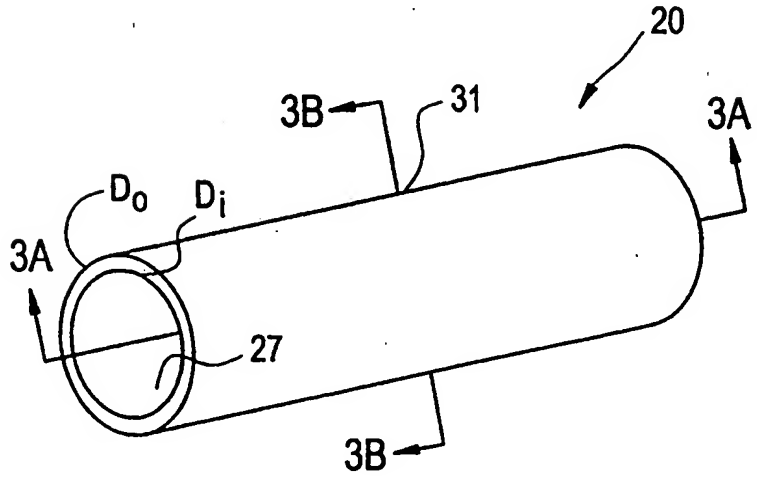


FIG. 3A

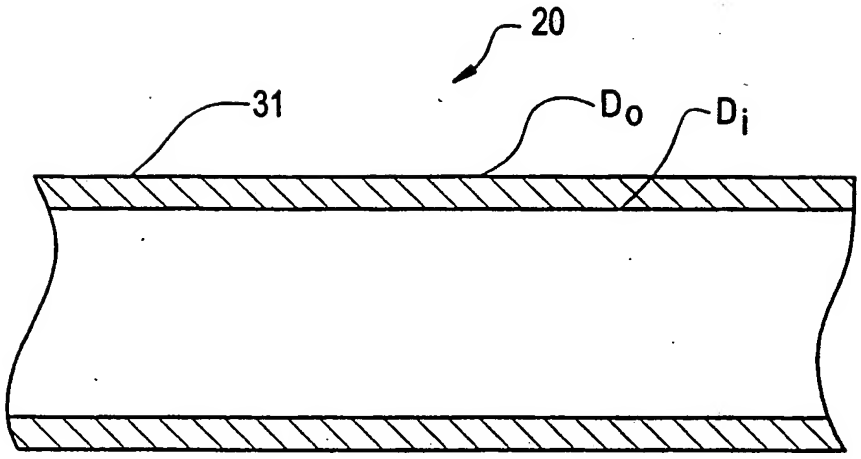


FIG. 3B

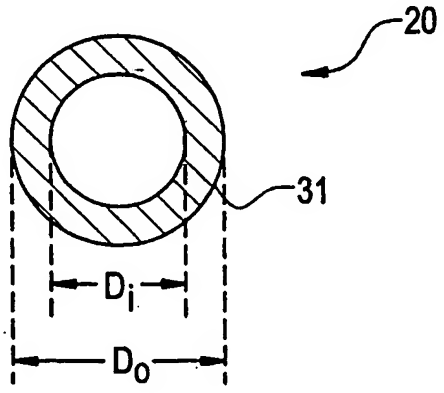


FIG. 4

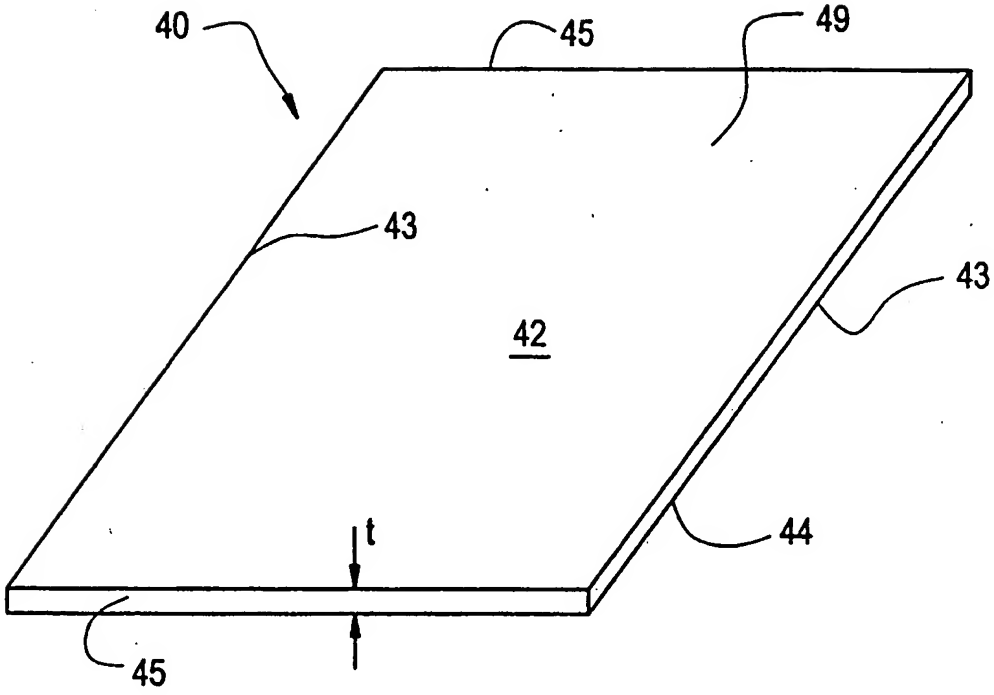


FIG. 5

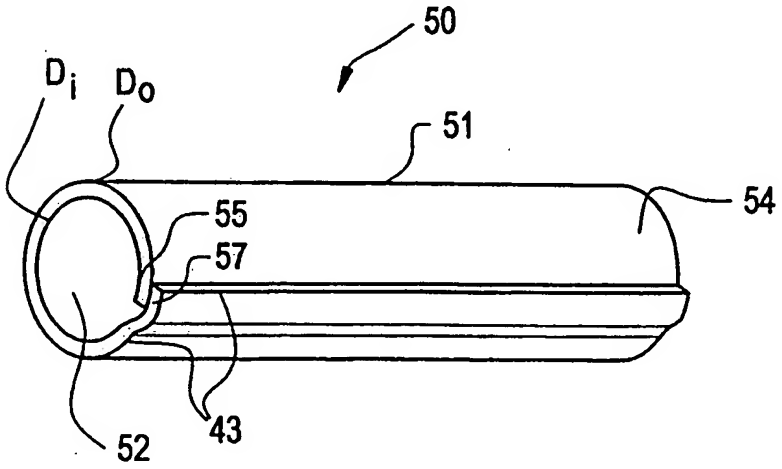


FIG. 6

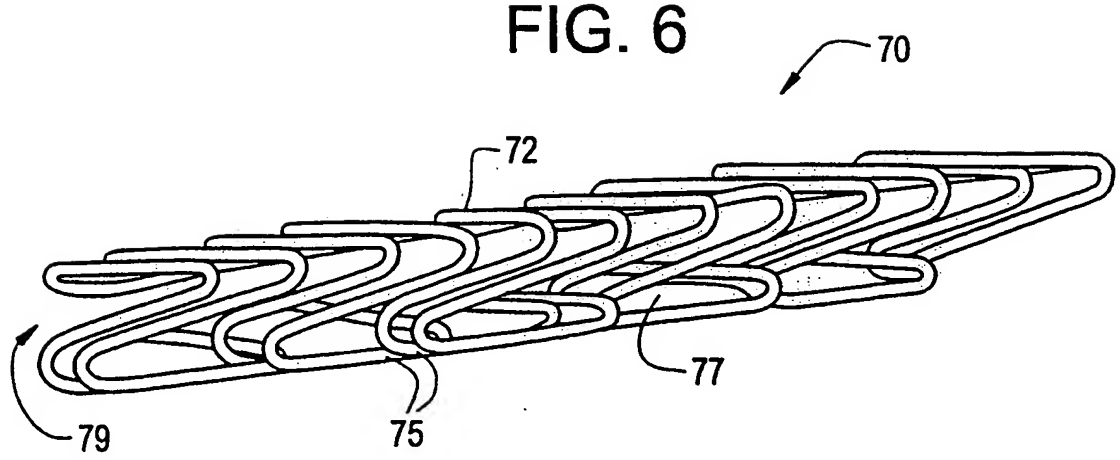


FIG. 7

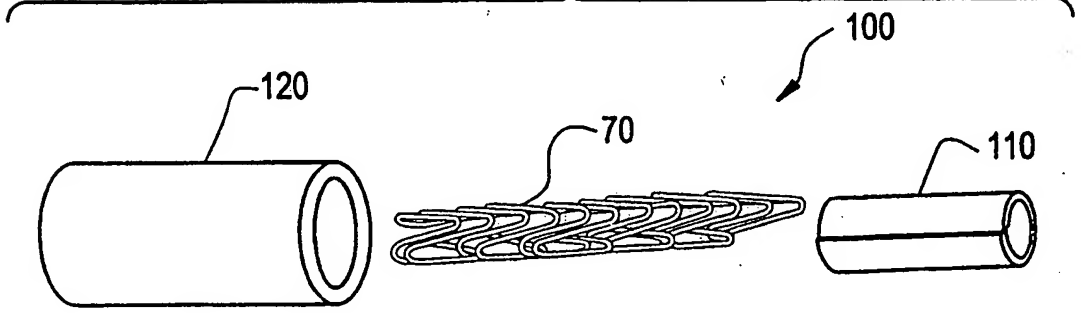


FIG. 8

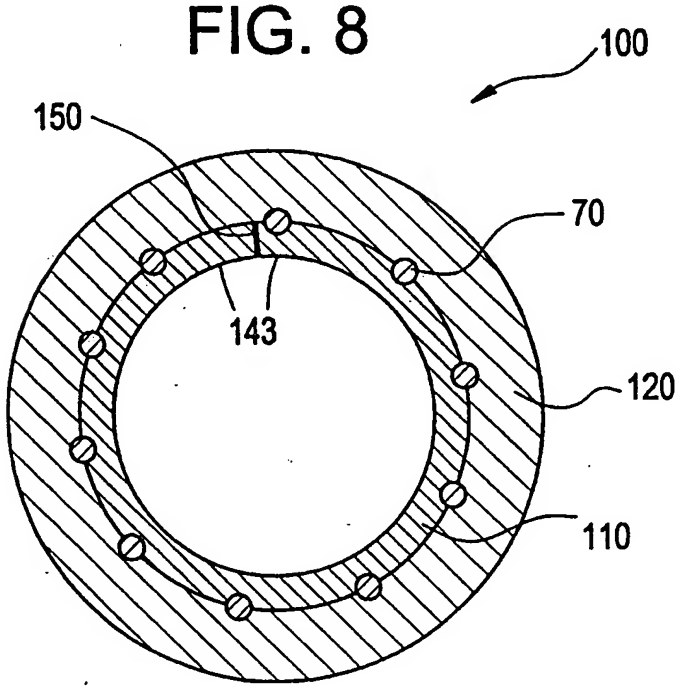


FIG. 9

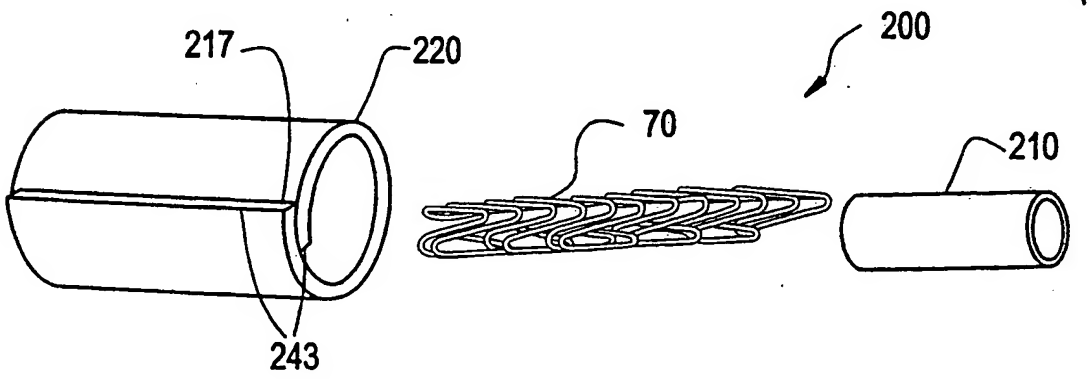
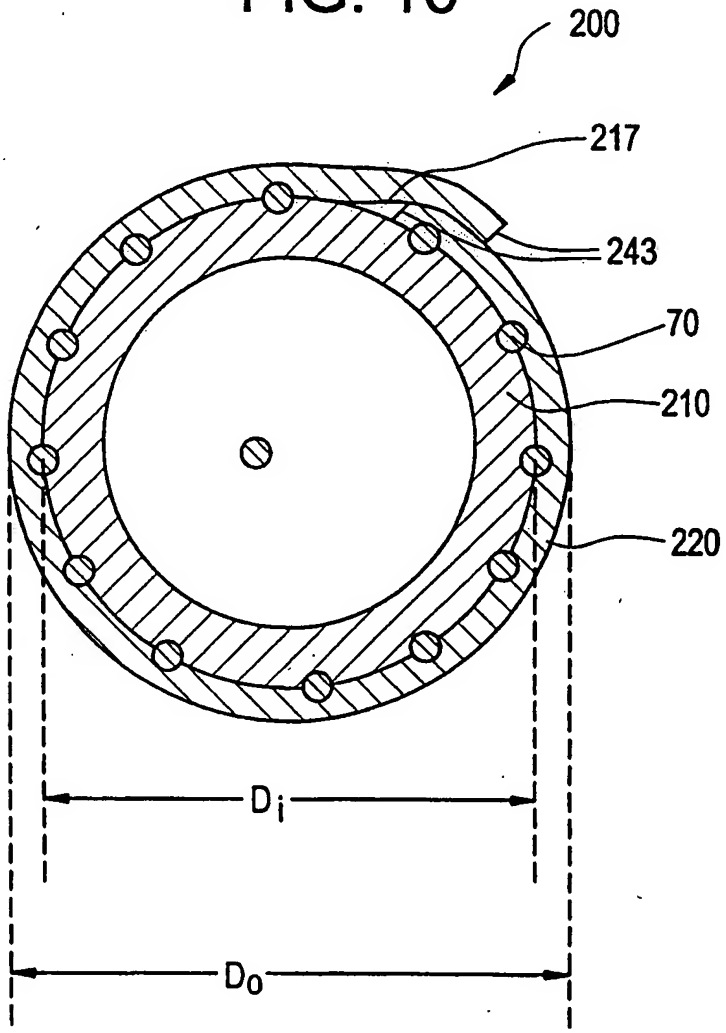


FIG. 10



INTERNATIONAL SEARCH REPORT

national Application No
PCT/US 00/23917

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 38947 A (SCIMED LIFE SYSTEMS, INC.) 11 September 1998 (1998-09-11) page 14, line 9 - line 13; figures	1-23

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 December 2000	21/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No
PCT/US 00/23917

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9838947 A	11-09-1998	EP 1011529 A	28-06-2000
		US 6139573 A	31-10-2000